04-05-04

1639

Docket No.: 441472000500
(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:
H. Ralph SNODGRASS

Application No.: 09/881,526 Group Art Unit: 1639

Filed: June 14, 2001 Examiner: B. Celsa

For: TOXICITY TYPING USING LIVER STEM CELLS

RESPONSE TO RESTRICTION REQUIREMENT

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

This is in response to the Office Action mailed October 3, 2003 (part of Paper No. 8) setting forth a Restriction Requirement, for which a response was due on November 3, 2003. Filed herewith is a Petition and fee for a five month extension of time, thereby extending the deadline for response to April 3, 2004. Accordingly, this response is timely filed.

INTERVIEW SUMMARY

Pursuant to 37 C.F.R. §1.133(b), provided herein is Applicant's Statement of the substance of the telephonic interview held March 26, 2004 with Examiner Celsa. As a preliminary matter, Applicant thanks Examiner Celsa for the courtesy of the helpful telephonic interview with Applicant's representatives Gladys Monroy and Carol Gruppi (the undersigned).

The subject of the telephonic interview was the Restriction Requirement and Species Election Requirement set forth in the Office Action dated October 3, 2003. Applicant's representatives discussed with the Examiner the complexity of the Restriction Requirement (33 groups for 41 claims) and Species Election Requirement (4 way species election) and their intent to traverse both the Restriction Requirement and Species Election Requirement. The Examiner was understanding of the complexity of the Restriction Requirement and Species Election Requirement. The Examiner indicated that he was open to consolidating and/or modifying the groups set forth in the Restriction Requirement as well as the Species Election Requirement.

RESTRICTION REQUIREMENT

The Office Action sets forth a Restriction Requirement requesting Applicant to elect one of the following inventions for prosecution on the merits:

I. Claims 1, 3, 4-6, drawn to a method of creating a molecular profile comprising alterations in gene expression of a chemical composition using mammalian liver stem cells, Classified in Class 702, Subclass19.

II. Claims 1, 3, 7-9, drawn to a method of creating a molecular profile comprising alterations in protein expression of a chemical composition using mammalian liver stem cells, Classified in Class 702, Subclass 27.

III. Claims 2, 3, 4-6, drawn to a method of compiling a library of molecular profiles comprising alterations in gene expression of chemical compositions having predetermined toxicities using mammalian liver stem cells, Classified in Class 435, Subclass Digest 46.

IV. Claims 2, 3, 7-9, drawn to a method of compiling a library of molecular profiles comprising alterations in protein expression of chemical compositions having predetermined toxicities using mammalian liver stem cells, Classified in Class 435, Subclass Digest 46.

V. Claims 2, 3, 10, 11, 19, and 20, drawn to a method of compiling a library of molecular profiles of chemical compositions that are therapeutic agents, neurotoxins, renal toxins, hepatic toxins, hematopoietic cell toxins, or myotoxins having predetermined toxicities using human liver stem cells, Classified in Class 424, Subclass 236.1.

VI. Claims 2, 3, 10, 12, 19 and 20, drawn to a method of compiling a library of molecular profiles of chemical compositions that are toxic to cells of one or more reproductive organs, teratogenic agents, or carcinogens having predetermined toxicities using human liver stem cells, Classified in Class 424, Subclass 236.1.

VII. Claims 2, 3, 10, 13, 19 and 20, drawn to a method of compiling a library of molecular profiles of chemical compositions that are agricultural chemicals, cosmetics, or environmental agents having predetermined toxicities using human liver stem cells, Classified in Class 424, Subclass 236.1.

VIII. Claims 2, 3, 14, 16, 19 and 20, drawn to a method of compiling a library of molecular profiles of chemical compositions that are animal therapeutics, neurotoxins, renal toxins, hepatic toxins, hematopoietic cell toxins, or myotoxins having predetermined toxicities using non-human mammalian liver stem cells, Classified in Class 424, Subclass 236.1.

IX. Claims 2, 3, 14, 17, 19 and 20, drawn to a method of compiling a library of molecular profiles of chemical compositions that are toxic to cells of one or more reproductive

organs, teratogenic agents, or carcinogens having predetermined toxicities using non-human mammalian liver stem cells, Classified in Class 424, Subclass 236.1.

X. Claims 2, 3, 14, 18, 19 and 20, drawn to a method of compiling a library of molecular profiles of chemical compositions that are agricultural chemicals, cosmetics, or environmental agents having predetermined toxicities using non-human mammalian liver stem cells, Classified in Class 424, Subclass 236.1.

XI. Claims 2, 3, 15, 16, 1 9 and 20, drawn to a method of compiling a library of molecular profiles of chemical compositions that are animal therapeutics, neurotoxins, renal toxins, hepatic toxins, hematopoietic cell toxins, or myotoxins having predetermined toxicities using rodent liver stem cells, Classified in Class 424, Subclass 236.1.

XII. Claims 2, 3, 15, 17, 19 and 20, drawn to a method of compiling a library of molecular profiles of chemical compositions that are toxic to cells of one or more reproductive organs, teratogenic agents, or carcinogens having predetermined toxicities using rodent liver stem cells, Classified in Class 424, Subclass 236.1.

XIII. Claims 2, 3, 15, and 18-20, drawn to a method of compiling a library of molecular profiles of chemical compositions that are agricultural chemicals, cosmetics, or environmental agents having predetermined toxicities using rodent liver stem cells, Classified in Class 424, Subclass 236.1.

XIV. Claims 21, 24 and 25 in part, 26, drawn to a method of typing the toxicity of a test chemical composition that is selected from therapeutic agents, neurotoxins, renal toxins, hepatic toxins, hematopoietic cell toxins, or myotoxins that are known or unknown using human liver stem cells, Classified in Class 424, Subclass 9.2.

XV. Claims 21, 24 and 25 in part, 27 drawn to a method of typing the toxicity of a test chemical composition that is selected from agents that are toxic to cells of one or more reproductive organs, teratogenic agents, or carcinogens that are known or unknown using human liver stem cells.

XVI. Claims 21, 24 and 25 in part, 28, drawn to a method of typing the toxicity of a test chemical composition that is selected from agricultural chemicals, cosmetics, or environmental agents that are known or unknown using human liver stem cells, Classified in Class 424, Subclass 9.2.

XVII. Claims 21, 24 in part, 29, 31, drawn to a method of typing the toxicity of a test chemical composition that is selected from agents that are animal therapeutics, neurotoxins, renal toxins, hepatic toxins, hematopoietic cell toxins, or myotoxins that are known or unknown using non-human mammalian liver stem cells, Classified in Class 424, Subclass 9.2.

XVIII. Claims 21, 24 in part, 29, 32, drawn to a method of typing the toxicity of a test chemical composition that is selected from agents that are toxic to cells of one or more reproductive organs, teratogenic agents, or carcinogens that are known or unknown using non-human mammalian liver stem cells, Classified in Class 424, Subclass 9.2.

XIX. Claims 21, 24 in part, 29, 33, drawn to a method of typing the toxicity of a test chemical composition that is selected from agents that are agricultural chemicals, cosmetics, or environmental agents that are known or unknown using non-human mammalian liver stem cells, Classified in Class 424, Subclass 9.2.

XX. Claims 21, 24 in part, 30, 31, drawn to a method of typing the toxicity of a test chemical composition that is selected from agents that are animal therapeutics, neurotoxins, renal toxins, hepatic toxins, hematopoietic cell toxins, or myotoxins that are known or unknown using rodent liver stem cells, Classified in Class 424, Subclass 9.2.

XXI. Claims 21, 24 in part, 30, 32, drawn to a method of typing the toxicity of a test chemical composition that is selected from agents toxic to cells of one or more reproductive organs, teratogenic agents, or carcinogens that are known or unknown using rodent liver stem cells, Classified in Class 424, Subclass 9.2.

XXII. Claims 21, 24 in part, 30, 33, drawn to a method of typing the toxicity of a test chemical composition that is selected from agents that are agricultural chemicals, cosmetics, or environmental agents that are known or unknown using rodent liver stem cells, Classified in Class 424, Subclass 9.2.

XXIII. Claims 22, 23, 24 and 25 in part, 26, drawn to a method of typing or ranking toxicity of (a) test chemical composition(s), known or unknown, that are therapeutic agents, neurotoxins, renal toxins, hepatic toxins, hematopoietic cell toxins, or myotoxins using human liver stem cells, Classified in Class 424, Subclass 9.2.

XXIV. Claims 22, 23, 24 and 25 in part, 27, drawn to a method of typing or ranking toxicity of (a) test chemical composition(s), known or unknown, selected from agents toxic to cells of one or more reproductive organs, teratogenic agents, or carcinogens using human liver stem cells, Classified in Class 424, Subclass 9.2.

XXV. Claims 22, 23, 24 and 25 in part, 28, drawn to a method of typing or ranking toxicity of (a) test chemical composition(s), known or unknown, selected from agents that are agricultural chemicals, cosmetics, or environmental agents using human liver stem cells, Classified in Class 424, Subclass 9.2.

XXVI. Claims 22, 23, 24 in part, 29, 31, drawn to a method of typing or ranking toxicity of (a) test chemical composition(s), known or unknown, selected from agents that are animal therapeutics, neurotoxins, renal toxins, hepatic toxins, hematopoietic cell toxins, or myotoxins, using non-human mammalian liver stem cells, Classified in Class 424, Subclass 9.2.

XXVII. Claims 22, 23, 24 in part, 29, 32, drawn to a method of typing or ranking toxicity of (a) test chemical composition(s), known or unknown, selected from agents toxic to cells of one or more reproductive organs, teratogenic agents, or carcinogens using non-human mammalian liver stem cells, Classified in Class 424, Subclass 9.2.

XXVIII. Claims 22, 23, 24 in part, 29, 33, drawn to a method of typing or ranking toxicity of (a) test chemical composition(s), known or unknown, selected from agents that are agricultural chemicals, cosmetics, or environmental agents using non-human mammalian liver stem cells, Classified in Class 424, Subclass 9.2.

XXVIX. Claims 22, 23, 24 in part, 30, 31, drawn to a method of typing or ranking toxicity of (a) test chemical composition(s), known or unknown, selected from agents that are animal therapeutics, neurotoxins, renal toxins, hepatic toxins, hematopoietic cell toxins, or myotoxins, using rodent liver stem cells, Classified in Class 424, Subclass 9.2.

XXX. Claims 22, 23, 24 in part, 30, 32, drawn to a method of typing or ranking toxicity of (a) test chemical composition(s), known or unknown, selected from agents toxic to cells of one or more reproductive organs, teratogenic agents, or carcinogens using rodent liver stem cells, Classified in Class 424, Subclass 9.2.

XXXI. Claims 22, 23, 24 in part, 30, 33, drawn to a method of typing or ranking toxicity of (a) test chemical composition(s), known or unknown, selected from agents that are agricultural chemicals, cosmetics, or environmental agents using rodent liver stem cells; Classified in Class 424, Subclass 9.2.

XXXII. Claims 34-37, drawn to an integrated system for comparing liver stem cell molecular profiles of a chemical composition a library of liver stem cell molecular profiles of chemical compositions having predetermined toxicities, Classified in Class 707, Subclass 3.

XXXIII. Claims 38-41, drawn to an integrated system for correlating the liver stem cell molecular profile and toxicity for a chemical composition, Classified in Class 707, Subclass 9.2.

The Office Action states that claims 1-10, 14, 15, 19-25, 29 and 30 generic. In addition, the Office Action also states that claims 1, 2, 21, 22 and 23 are unsearchable as they are "generic to a plurality of disclosed patentably distinct species" (Office Action page 10) and requests Applicant to elect a single disclosed species for prosecution on the merits from each group listed below:

1. In vitro method versus in vivo method;

2. a mammalian species,

3. a class of chemical compound;

4. a single compound from the elected class of group (3).

RESPONSE TO THE RESTRICTION REQUIREMENT AND SPECIES ELECTION REQUIREMENT

Applicant respectfully traverses the Restriction and Species Election Requirement, and respectfully requests that the Restriction Requirement and/or Species Election Requirement be reviewed and either withdrawn or modified for the reasons set forth below.

A restriction requirement is proper if there would be a serious search and examination burden on the Office absent the restriction requirement. See MPEP § 803. Applicant respectfully submits that it would not be unduly burdensome to search the claims of Groups V-XXXI together as the Office has placed the claims of Groups V-XXXI in the same class (Class 424). Likewise, Applicant submits that it would not be unduly burdensome to search the claims of Groups V-XIII together as the Office has placed the claims of Groups V-XIII in the same class and subclass (Class 424; subclass 46) or the claims of Groups XIV –XXXI together as the Office has placed the claims Groups XIV–XXXI in the same class and subclass (Class 424; subclass 9.2). Applicant also respectfully submits that it would not be unduly burdensome for the Office to search the four species groups set forth by the Office together. Accordingly, Applicant respectfully submits that there is no undue search burden and requests withdrawal or modification of the instant Restriction Requirement and/or Species Election Requirement.

In the event that that the Restriction Requirement and Species Election Requirement are maintained, Applicants provisionally elect the claims of Group III (claims 2, 3, 4-6) for prosecution on the merits. For the species election, Applicant provisionally elect the in vitro methods for Group

1; human as the mammalian species for Group 2; heterocyclic compounds as the class of chemical compounds for Group 3; and therapeutic and/or potential therapeutic compounds as the single compound from Group 3 for Group 4. Claims readable on the species elections are 2-20.

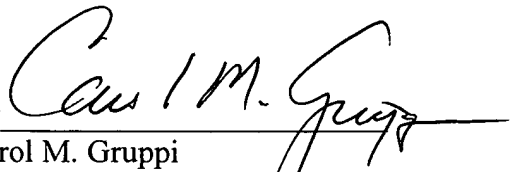
CONCLUSION

Applicant respectfully requests examination of the elected subject matter on the merits. Applicant expressly reserves his right under 35 U.S.C. § 121 to file a divisional application directed to the nonelected subject matter during the pendency of this application, or an application claiming priority from this application.

In the unlikely event that the transmittal form is separated from this document and the Patent Office determines that an extension and/or other relief is required, Applicant petitions for any required relief including extensions of time and authorize the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 03-1952** referencing (441472000500). However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

Dated: April 1, 2004

Respectfully submitted,

By 

Carol M. Gruppi
Registration No.: 37,341
MORRISON & FOERSTER LLP
755 Page Mill Road
Palo Alto, California 94304

(650) 813-5777